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## About

### **Emdogain®**

#### ○ Emdogain®

Gel

#### ○ Background

#### ○ Background

- The

Key

to

Biomimicry

in

Periodontics

#### ○ Safety

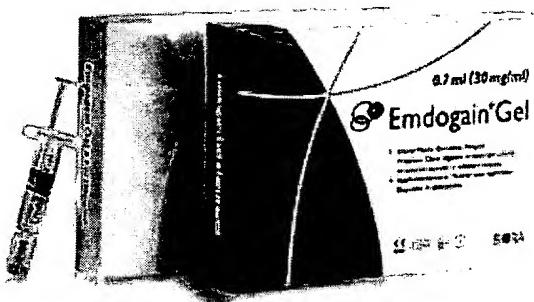
and

Efficacy

#### ○ Emdogain® Gel

Emdogain is intended as an adjunct to periodontal surgery for topical application onto exposed root surfaces. After a single gel application, Emdogain leaves only a resorbable protein matrix on the root surface.

Emdogain Gel is a stabilized formulation of pre-mixed Emdogain protein and the vehicle solution, Propylene Glycol Alginate. This is supplied in a pre-filled, ready to use syringe that is available in two sizes, one size (0.3 ml) for single defects, and another larger size (0.7 ml) for multiple defect cases. Each package is intended for use in one patient only.



Emdogain Gel can be applied directly from the syringe. This means no mixing or extra chair time is required. It is designed for use as a first-line treatment for regenerative therapy. With no additional chair time or added equipment required, Emdogain answers today's demands on clinical time and resources.

#### ○ Background

Severe periodontal disease affects about 35 percent of people over 55 years. Emdogain aims at an annual market worldwide of about five million surgical procedures in patients with severe periodontal disease.

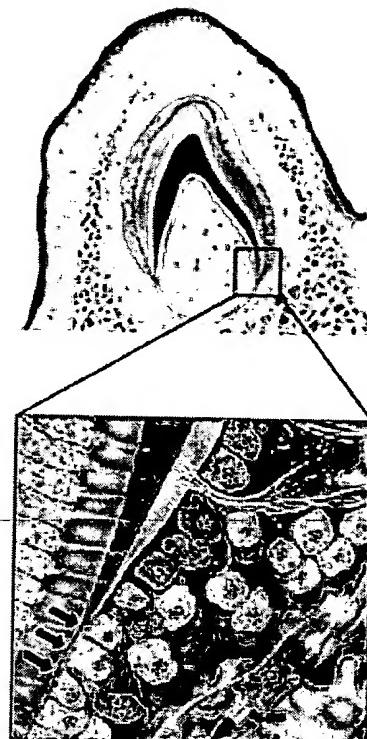
## ④ Background - The Key to Biomimicry in Periodontics

Biomimicry has been called the quest for innovation inspired by nature. Although it is a relatively new concept, products like Emdogain are defining this exciting new field of endeavor.

Emdogain found its beginnings over a decade ago when a scientific breakthrough in the basic biology of tooth development revealed a native complex of enamel matrix proteins and the key role they play in the development of tooth-supporting tissues. These "matrix proteins" mediate the formation of acellular cementum on the root of the developing tooth, providing a foundation for all of the necessary tissues associated with a true functional periodontal attachment.

Emdogain is comprised of amelogenin proteins that self-assemble to create a matrix. In humans, amelogenins are found in the early stages of enamel formation, as well as in the development of acellular cementum and its associated tooth attachment apparatus. Recent studies have shown the structure of amelogenins to have been remarkably well-conserved throughout evolution and functionally consistent in many species. Therefore, although the matrix proteins in Emdogain are of porcine origin, they are considered as "self" when encountered by the human body.

With this simple discovery, biomimicry has found its way to periodontics, fueling a new generation in periodontal therapy, and making the restoration of lost tooth support an attainable outcome in the treatment of periodontitis.



Detail of the phase in which Hertwig's epithelial root sheath cells (blue) secrete enamel proteins (arrows). After the formation of protein matrix on the root surface, cementum (light blue) thus providing an anchor for the collagen fibres.

## Safety and Efficacy

The safety of Emdogain has been thoroughly documented. A comprehensive toxicology program including acute and chronic studies, in vitro mutagenicity studies, reproductive toxicology tests, and several additional toxicology studies have been carried out. The potential for sensitization and other immunological reactions in humans was also examined. No immunological or allergic reactions were found.

Clinical documentation for Emdogain has been obtained from a series of strictly designed studies in the U.S. and Sweden. Followed for over three years, patients have shown clinically significant improvement in Emdogain treated teeth compared to control surgery by achieving statistical significance for probing pocket reduction, clinical attachment gain, and radiographic bone gain.

Clinical studies show that patients with deep periodontal pockets (more than 6 mm) of the 1-wall and 2-wall type may expect to achieve significant alveolar bone regain (average of 60-70% defect fill).